510(k) Summary for exSALT™ SD7 Wound Dressing

1. Trade (Proprietary) Name

exSALT™ SD7 Wound Dressing

JUL 30 2009

2. Common Name

Wound or Burn Dressing

3. Contact Information

Address: Exciton Technologies Inc.
Suite 4232-10230 Jasper Avenue
Edmonton, Alberta T5J 4P6
Canada

Phone: (780) 248-5868
Fax: (780) 248-5878

Contact: Rod Precht
President and CEO

Date of 510(k) Summary Preparation: June 29, 2009

4. Device Classification & Panel

A final classification for wound/burn dressings has not been implemented; Class II has been proposed by the General & Plastic Surgery Devices Panel.

5. Predicate Device(s)

Acticoat® 7 Dressing (K001519)

6. Device Description

The exSALT™ SD7 Wound Dressing consists of 2 outer layers of HDPE with an inner layer of absorbent polyester, all coated with silver. The dressing is available in various sizes and can be cut to size. Silver in the exSALT™ SD7 Wound Dressing kills bacteria which are in direct contact with the dressing.

7. Intended Use

The exSALT™ SD7 Wound Dressing is indicated for the management of partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

8. Summary of Substantial Equivalence

The labeled indications and directions for use of the exSALT™ SD7 Wound Dressing are equivalent to those of the predicate device, Acticoat® 7 Dressing. The design, materials, and manufacturing methods are similar to those of the predicate device and do not raise any new issues concerning safety or effectiveness.

a) Summary of Technological Characteristics

The exSALT™ SD7 Wound Dressing consists of 2 outer layers of HDPE with an inner layer of absorbent polyester which are all silver-coated, while the predicate, Acticoat® 7 Dressing, consists of 3 layers of silver-coated HDPE alternating with two inner layers of absorbent polyester/rayon. Importantly, the skin-contacting materials in both the exSALT™ SD7 Wound Dressing and the predicate are the same. The absence of an extra layer of silver-coated HDPE in the exSALT™ SD7 dressing as compared to the predicate, does not affect the performance of the device as demonstrated by the results of physical, efficacy, and biocompatibility testing.

Silver is deposited on the exSALT™ SD7 Wound Dressing using an aqueous chemistry (emersion) approach, while physical vapor deposition (PVD) is used with the predicate. Both the PVD process and the emersion process produce oxidized silver species adherent to the substrate. This difference in application of the silver to the dressing does not affect the efficacy or safety of the device as demonstrated by the results of the bactericidal and antimicrobial efficacy testing, and biocompatibility testing. Both the exSALT™ SD7 Wound Dressing and the predicate are sterilized by gamma irradiation.

b) Summary of Performance Data

The following performance tests were conducted on the exSALT™ SD7 Wound Dressing:

- Absorptive Capacity
- Moisture Content
- Drop Penetration
- Adhesion

- Abrasion
- Silver Content
- Anti-microbial (Bacterial) Effectiveness
- Bactericidal Effectiveness
- Biocompatibility
- Biological Reactivity

Absorptive capacity, moisture content, adhesion, and abrasion characteristics were found to be substantially equivalent to the predicate.

While the amount of silver ion release from the exSALT™ SD7 Wound Dressing is less than that of Acticoat® 7 dressing over similar time periods, this does not affect the antimicrobial properties of the device. Antimicrobial effectiveness and bactericidal efficacy against *Pseudomonas aeruginosa* and *Staphylococcus aureus* were found to be the same when comparing the exSALT™ SD7 Wound Dressing and the predicate, tested under similar conditions.

The exSALT™ SD7 Wound Dressing showed no new safety concerns relative to biocompatibility. It was shown to be non-toxic, non-irritant, and does not elicit a sensitization response.

The exSALT™ SD7 Wound Dressing is substantially equivalent to the Acticoat® 7 Dressing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Exciton Technologies, Inc.
% Intrinsik Health Sciences, Inc.
Ms. Sandra Reis
6605 Hurontarioi Street
Mississauga, Ontario L5T0A3
Canada

JUL 30 2009

Re: K083870
Trade/Device Name: exSALT™ SD7 Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 30, 2009
Received: July 1, 2009

Dear Ms. Reis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

exSALT™ SD7 Wound Dressing Indication for Use

510(k) Number: K083870

Device Name: exSALT™ SD7 Wound Dressing

Indication For Use:

The exSALT ™ SD7 Wound Dressing is indicated for the management of partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

Prescription Use ___X___ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MSM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083870